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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.		
10/807,089	03/23/2004	Wenying Li	LD0154 DIV1	3840		
23914	7590 08/28/2006		EXAM	EXAMINER		
LOUIS J. V	WILLE MYERS SQUIBB COMP.	LILLING, HERBERT J				
	EPARTMENT	ART UNIT	PAPER NUMBER			
POBOX 4	000	1651	1651			
PRINCETO	N, NJ 08543-4000		DATE MAILED: 08/28/200	DATE MAILED: 08/28/2006		

Please find below and/or attached an Office communication concerning this application or proceeding.

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  Extensions of time may be available under the provision of 37 CPR 1.13(a). In ne event, however, may a reply be timely filed after OIX (9) MONTHS from the mailing date of this communication.  Failute or recy whilin the set or extended pérido for review will, by statute, cause the application to become ARADHORD (3) U.S. C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any semined pates than 30 per provided by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any semined pates than 30 per provided by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any semined pates than 30 per provided by the Office and 10 per provided by the Office Action or form PTO-152.  Disposition of Claim(s) 1-17 is/are pending in the application and/or election requirement.  4) Claim(s) 1-17 is/are pending in the application of the Office Action or form PTO-152.  Claim(s) 1-17 is/are pending in the application and/or election requirement.  Application Papers  9) The specification is objected to by the Examiner.  Application Papers  9) The specification is objected to by the Examiner.  Application Papers  10) The drawing(s) filed on		Application No.	Applicant(s)					
HERBERT J. LILLING  A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  Before the common by a validation in the processor of 3 CFR 1.184(s). Inno erect, however, in any steply be timely find  If NO period for reply is specified above, the maximum statutory period will apply and will expire SM (6) MONTHS from he mailing date of this communication. Failure to sept within the set or exercised period to reply will be set or exercised period to reply set of the communication, even if there find the communication, even if there is a set of the communication, even if the reply field, may reduce any set of the communication, even if the set of the set of the set of the communication, even if the set of the set	Office Action Summan	10/807,089						
The MALING DATE of this communication appears on the cover sheet with the correspondence address — Period for Reply  A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  Examinor to the rary by existed under the provision of 37 CFR 11-30(i). In or event, nower, rays a reply be timely filled  # NO prood for reply is specified above, the maximum etialutory period will apply and will expire SIX (8) MONTHS from the mailing date of this communication, Fallur to represented period for reply will, by statuke, capit the specification for SIX (5) (15). A reply received by the Office list than three motions after the mailing date of this communication, even if timely filed, may reduce any search plants them alloquence. Set 37 CR 17-180(i).  **Status**  1) ★ Responsive to communication(s) filled on **OB August 2008** 2a) ★ This action is FINAL.  2b ★ This action is finAL.  2b ★ This action is non-final.  3) ★ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle**, 1935 C.D. 11, 453 O.G. 213.  **Disposition of Claims**  4) ★ Claim(s) **L-17** is/are pending in the application.  4a) Of the above claim(s) **1-17** is/are withdrawn from consideration.  5b ★ Claim(s) **1-17** is/are pending in the application.  4a) Of the above claim(s) **1-17** is/are withdrawn from consideration.  5c ★ Claim(s) **1-17** is/are by is/are allowed.  Claim(s) **1-18** is/are 5-18** is/are allowed.  The drawing(s) filed on **1-18** is/are 5-18** is/are	Office Action Summary	Examiner	Art Unit					
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Exercisions of time may be available under the provisions of 37 CPR 1-35(b). In no event, however, may a risky be timely filed.  - Exercisions of time may be available under the provisions of 37 CPR 1-35(b). In no event, however, may a risky be timely filed.  - If No period to reply is specified above, the maximum studius ported will apply and will expire (x) (M NOTH'S from the making date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S. C. § 133). Any redy received by this Official them the time the making date of this communication, even if timely filed, may reduce any survey patient term adjustment. See 37 CPR 1-76(b).  - Status  1) □ Responsive to communication(s) filled on 08 August 2005.  2a) □ This action is FINAL.  2b) □ This action is FINAL.  2c) □ This action is FINAL.  2d) □ This action is FINAL.  4) □ Claim(s) 1-17 Is/are pending in the application.  4a) □ Of the above claim(s) 14-17 Is/are withdrawn from consideration.  5□ Claim(s) 1-3 and 5-8 Is/are allowed.  - Claim(s) 1-3 and 5-8 Is/are allowed.  - Claim(s) 1-3 and 5-8 Is/are rejected.  - □ Claim(s) 1-3 and 5-8 Is/are rejected.  - □ Claim(s) 1-3 and 5-8 Is/are rejected.  - □ Claim(s) 1-4-17 are subject to restriction and/or election requirement.  - Application Papers  9) □ The specification is objected to by the Examiner.  10 □ The drawing(s) filed on is/are: a) □ accepted or b) □ objected to by the Examiner.  - Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  Replacement drawing sheet								
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1. Receipt is acknowledged of the election response filed August 08,

2006.

2. Applicant has elected Group I, Claims 1-13.

Claims 14-17 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on August 08, 2006.

3. Claims 4,9 (dependent claims 10-12) and 13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention with respect to the availability of the strain ATCC 35203 in accordance with the following requirements:

## U.S. Patent Rules of Deposits

It is apparent that the strain is required to practice the claimed invention(s) as recited in the claims. As a required element it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If it is not so obtainable or available, the enablement requirements of 35 U.S.C. 112, first paragraph, may be satisfied by a deposit of strain in accordance with U.S. Rules. See 37 C. F. R. 1.802.

The specification does not provide a repeatable method for obtaining the strain and it does not appear to be a readily available material. Deposit of strain would satisfy the enablement requirements of 35 U.S.C. 112. If a deposit has been made, Applicant is required to meet the necessary criteria of the deposit rules in accordance with 37 CFR 1.801-37 CFR 1.809.

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If a deposit has not been supplied or made under the Budapest Treaty, then an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty **and that all restrictions** imposed by the depositor on the availability to the public of the deposited material will be **irrevocably removed** upon the granting of a patent, would satisfy the deposit requirements, See 37 CFR 1.808.

If a deposit is not made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made at an acceptable depository and that the following criteria have been met:

a) During the pendency of the application, access to the deposit will be afforded to one determined by the Commissioner to be entitled thereto;

b) all restrictions imposed by the depositor on the availability to the public of the deposited material <u>will be irrevocably</u> removed upon the granting of a patent;

c) the deposit will be maintained for a term of at least thirty (30) years and at least five (5) years after the most recent request for the furnishing of a sample of the deposited material;

d) a viability statement in accordance with the provisions of 37 CFR 1.807;

and

e) the deposit will be replaced should it become necessary due to inviability, contamination or loss of capability to function n the manner described in the specification.

In addition, the identifying information set forth in 37 CFR 1.809(d) should be added to the specification, See 37 CFR 1.803-37 CFR 1.809 for additional explanations of these requirements.

<u>Please note</u> that the mere reference to a deposit or the biological material itself in any document or publication does not necessarily mean that the deposited biological material is readily available. Even a deposit made under the Budapest Treaty and referenced in a United States or foreign patent document would not necessarily meet the test for known and readily available unless the deposit was made under conditions that are consistent with those specified in these rules, including the provision that requires, with

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one possible exception (37 CFR 1.808(b)), that all restrictions on the accessibility be irrevocably removed by the applicant upon the granting of the patent. Ex parte Hildebrand, 15 USPQ2d 1662 (Bd. Pat. App. & Int. 1990).

The record clearly indicates that the strain ATCC 35203 has been known since 1983 and that Applicant has stated in the specification that the strain was bought from the ATCC. Based on the claimed language this Examiner is required to follow the guidelines and reject the claim absent as indicated in the above paragraph that any restrictions must be removed upon the granting of a patent-which also covers strains not owned by the present applicant(s). However, if the strain has been deposited in additional depositories, the office has considered in the past that the availability of the strain has been considered to be accessible without this requirement by others.

- 4. The prior art of record do not anticipate the claimed inventions. In addition, the references alone or further in view of each other do not suggest or motivate one of ordinary skilled in the art to hydroxylate a methyl grouping at the 26 position of the specific epothilones as claimed. Thus, Claims 1-3 and 5-8 are allowed over the art of record as well as enabling for other strains than the rejected strain ATCC 35203, which includes ATCC PTA-1043.
- 5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Examiner Lilling whose telephone number is 571-272-0918** and **Fax Number** is (703) 872-9306 or SPE Michael Wityshyn whose telephone number is 571-272-0926. Examiner can be reached Monday-Thursday from about 5:30 A.M. to about 3:00 P.M. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Information regarding the status of an application may be obtained from the Patent Application information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <a href="http://portal.uspto.gov/external/portal/pair">http://portal.uspto.gov/external/portal/pair</a>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

H.J.Lilling: HJL (571) 272-0918 Art Unit <u>1651</u> August 22, 2006

> Dr. Nerbert J. Lilling Primary Examiner

Group 1600 Art Unit 1651